UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

RONNIE MOORE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 1:16-CV-0161
	)	
C.R. BARD, INC., JOHNSON & JOHNSON, and ETHICON, INC.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

This products liability action is before the Court on several pending motions. Previously, defendant C.R. Bard, Inc. (hereinafter "Bard") filed a motion to dismiss [Doc. 13] and defendants Johnson & Johnson and Ethicon, Inc. (collectively hereinafter "Ethicon") filed a motion for judgment on the pleadings [Doc. 17]. In response to those motions, plaintiff sought and was granted leave to amend his complaint [Doc. 36] and the amended complaint was filed on August 24, 2016 [Doc. 35]. In response, defendants Ethicon and Bard filed motions to dismiss [Docs. 37, 39 respectively] the amended complaint for failure to state any plausible claims against the defendants pursuant to Fed. R. Civ. P. 12(b)(6). Because the plaintiff's amended complaint supersedes the original complaint, *see In re Refrigerant Compressors Antitrust Litigation*, 731 F.3d 586, 589 (6th Cir. 2013), the first motion to dismiss and motion for judgment on the pleadings [Docs. 13, 17] will be **DENIED as moot**.

After considering the relevant briefs in support of and in opposition to the pending motions [Docs. 38, 40, 41, 42, 43], the Court finds that the remaining motions to dismiss [Docs. 37, 39] should be **GRANTED**.

I. Relevant Facts[1]

On April 25, 2016, plaintiff Ronnie Moore had a surgical repair of the left direct inguinal hernia during which two mesh products were implanted in his body [Doc. 35 at ¶ 12].[2] Defendants Ethicon and Bard "designed, manufactured, packaged, labeled, marketed, sold and distributed" the prolene mesh products that were used in plaintiff's hernia repair [*Id.* at ¶¶ 1, 4, 7]. Specifically, plaintiff alleges that Bard manufactured the product "3D Max" Mesh, large size of 10.8 cm by 16.0 cm, and Ethicon manufactured a prolene mesh product size 3" by 8" [*Id.* at ¶¶ 1, 7]. "Both products are made of polypropylene and are not medically safe to be implanted in the body" [*Id*. at ¶ 11]. Both products have been marketed as "a safe, effective, reliable, medical device" and "safer and more effective hernia treatment products" [*Id.* at ¶ 8]. Plaintiff claims that both defendants

[1]For the purposes of a motion to dismiss, the Court takes the factual allegations in the amended complaint [Doc. 35] as true. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (noting that, "when ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint").

[2]The amended complaint asserts that plaintiff's surgery occurred on April 25, 2016 [Doc. 35 at ¶ 12]. As the defendants have correctly noted, this cannot be true as the original complaint was filed on April 21, 2016 [Doc. 1-1]. In other words, plaintiff could not have a claim on April 21 for injuries occurring as a result of an April 25 surgery. Defendants also note that Magistrate Judge Steger directed plaintiff to correct the date of the surgery in his amended complaint [Doc. 36 at ¶ 3], but plaintiff did not do so.

"omitted the risks, dangers, defects, and disadvantages" of their respective products when advertising, promoting, marketing, and distributing the products [*Id*. at ¶¶ 9—10].

Following his hernia repair surgery, plaintiff claims his condition "has worsened due to complications of one or both mesh products" [*Id*. at ¶ 13]. He has "lost feeling in most of his left leg" and has pain in the surrounding areas [*Id*.]. "Plaintiff has limited mobility and cannot perform basic tasks" [*Id*.]. Plaintiff has suffered from seizures and erectile dysfunction [*Id*.]. Plaintiff claims that the mesh products have "caused severe damage to the Plaintiff's abdomen region and leg around where the hernia occurred" [*Id*. at ¶ 20]. Plaintiff claims that additional medical treatment has been unable to determine a remedy for his problems and that removal of the mesh products is impossible [*Id*. at ¶¶ 14, 18(i)].

Plaintiff asserts four counts against both defendants: (1) strict products liability [*Id*. at ¶¶ 29—35]; (2) negligence [*Id*. at ¶¶ 36—41]; (3) failure to warn [*Id*. at ¶¶ 42—46]; and (4) breach of express and implied warranty [*Id*. at ¶¶ 47—51]. Plaintiff claims that he has suffered personal injury, pain and suffering, emotional distress, and has endured permanent injury and will continue to incur medical expenses [*Id*. at ¶¶ 34, 40, 45, 50]. Plaintiff seeks compensatory and punitive damages [*Id*. at p. 9].

II. Standard of Review

Federal Rule of Civil Procedure 8(a)(2) sets out a liberal pleading standard, *Smith v. City of Salem*, 378 F.3d 566, 576 n.1 (6th Cir. 2004), requiring only "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the

[opposing party] fair notice of what the . . . claim is and the grounds upon which it rests,'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Detailed factual allegations are not required, but a party's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." *Twombly*, 550 U.S. at 555. "[A] formulaic recitation of the elements of a cause of action will not do," nor will "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In deciding a Rule 12(b)(6) motion to dismiss, a court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, draw all reasonable inferences in favor of the plaintiff, and determine whether the complaint contains "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007) (citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Determining whether a complaint states a plausible claim for relief will [ultimately] . . . be a context-specific task that requires th[is Court] to draw on its judicial experience and common sense." *Id.* at 679.

III. Analysis

The pending motions present similar arguments. First, both defendants argue that all of plaintiff's claims – strict liability, negligence, failure to warn, and breach of express and implied warranty – are encompassed by the Tennessee Products Liability Act

("TPLA"), Tenn. Code Ann. §§ 29-28-101 – 29-28-108 [Doc. 38 at pp. 4—5; Doc. 40 at pp. 11—17]. Plaintiff has not responded to or contested this argument. Both defendants also argue that the amended complaint does not contain specific factual allegations by which the Court could infer that a specific defect in one or both of the mesh products caused plaintiff's injuries [Doc. 38 at pp. 5—9; Doc. 40 at pp. 11—17]. Moreover, both defendants point out that the complaint generally alleges that both defendants are responsible for his injuries without alleging any specific defect in either product or a link between the alleged defect(s) and his injuries [Doc. 38 at pp. 6—9; Doc. 40 at pp. 13—17]. Bard also argues that plaintiff fails to allege that an alternative warning would have changed his unidentified physician's actions and that change would have prevented plaintiff's injuries [Doc. 40 at pp. 15—16].

Plaintiff contends that he has sufficiently alleged that the mesh products were defective and/or unreasonably dangerous, that the defect existed at the time the products left the manufacturers' control, and that plaintiff's injuries were proximately caused by the defendants' products [Doc. 41 at pp. 4—7]. Plaintiff points out that both defendants have been sued for problems with similar products [*Id.* at p. 7]. Plaintiff also argues that he has pled his claims with as much specificity as possible given the amount of information publicly available to him [*Id*. at pp. 7—9]. Attached to his response, plaintiff has submitted two information sheets for Bard 3DMax Mesh and Bard Mesh and one information sheet

on Ethicon Prolene as examples of the defendants' advertisements and contends that the products do not perform as promised [Docs. 41-1, 41-2].[3]

In reply, defendants reiterate that plaintiff's allegations are conclusory and insufficient to plausibly allege that the products were defective or that his injuries were a result of the defects [Docs. 42, 43]. The defendants also note that plaintiff does not address their arguments that he failed to distinguish his claims against them and that he cannot simply rely on forthcoming discovery to plead the specific facts of his medical condition, information which is within his purview. Bard notes that plaintiff does not respond to the arguments regarding the failure to warn or breach of warranty claims [Doc. 43 at pp. 2—3].

It is settled that each of plaintiff's counts is covered by the TPLA. *See Higgs v. Gen. Motors Corp.*, 655 F. Supp. 22, 23 (E.D. Tenn. 1985) ("Indeed, it makes no difference whether the complaint is couched in terms of negligence, strict liability or breach of warranty, it has generally been held in the State of Tennessee that in order for a plaintiff to recover under any theory of product liability, the plaintiff must establish that the product was defective and unreasonably dangerous at the time the product left the control of the manufacturer."). Thus, regardless of plaintiff's theories of recovery—which include strict liability, negligence, failure to warn, and breach of express and implied warranties —

[3]As noted by defendants, these documents are not attached to the amended complaint and "matters outside the pleadings" will not ordinarily be considered by the Court unless the motion is converted to one for summary judgment. Fed. R. Civ. P. 12(d). The Court does not find it appropriate to convert the pending motions to motions for summary judgment. The amended complaint alleges certain advertising claims about the products that are reflected in the information sheets [*see* Doc. 35 at ¶¶ 15—18], although the Court notes that Bard Mesh is not a product at issue in this case.

plaintiff must allege facts for the Court to infer that the mesh products were "defective" or "unreasonably dangerous" at the time they left the control of the manufacturer. *See King v. Danek Med., Inc.*, 37 S.W.3d 429, 435 (Tenn. Ct. App. 2000) ("Unless the product was in a defective condition or unreasonably dangerous when it left the control of [the manufacturer], there is no liability pursuant to [the TPLA]"); Tenn. Code Ann. § 29–28–105(a) ("A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.").

At this stage in the proceeding, plaintiff must allege facts for the Court to infer that: "(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008) (citing *King*, 37 S.W.3d at 435). Under the TPLA, a product is "defective" if the condition "renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code Ann. § 29–28–102(2). In addition, a product is "unreasonably dangerous" if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that he knew of its dangerous condition." Tenn. Code Ann. § 29–28–102(8); *see Jackson v. Gen. Motors Corp.*, 60 S.W.3d 800, 806 (Tenn. 2001) (the "consumer expectation test");

Johnson v. Manitowoc Boom Trucks, Inc., 484 F.3d 426, 428–29 (6th Cir. 2007) (the "prudent-manufacturer test").

In all product liability actions, "[a] plaintiff must show that there was something wrong with the product, and trace the plaintiff's injury to the specific defect." *King*, 37 S.W.3d at 435 (citations omitted). *See also Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976) (holding that in order to establish a defective design claim, the plaintiff must "trace the injury to some specific error in construction or design of the [product]" and that "in a products liability action in which recovery is sought under the theory of negligence, the plaintiff must establish the existence of a defect in the product just as he does in an action where recovery is sought under the strict liability theory or for breach of warranty, either express or implied.") (citations omitted). Thus, plaintiff must allege facts by which the Court can infer that the mesh products were defective, and that plaintiff's injuries were caused by the defective or unreasonably dangerous condition of the mesh products. In this case, plaintiff has failed to do both.

Plaintiff alleges that he has suffered injuries following the hernia surgery wherein defendants' products were implanted. The only allegation of defect is that "[b]oth products are made of polypropylene and are not medically safe to be implanted in the body" and that his "condition has worsened due to complications of one or both mesh products" [Doc. 35 at ¶¶ 11, 13]. However, the fact that the products are made from polypropylene and plaintiff allegedly suffered an injury from one or both of the mesh products does not show that the products were defective or unreasonably dangerous. *See Maness v. Boston Sci.*, 751 F. Supp. 2d 962, 969 (E.D. Tenn. 2010); *King*, 37 S.W. 3d at 435 ("[i]n a product

liability claim, the fact that a plaintiff is injured is not proof of a defect in the product" and "the failure or malfunction of the device, without more, will not make the defendant liable"). Plaintiff has presented no evidence or authority that the use of polypropylene makes the products per se defective or unreasonably dangerous. Without more, plaintiff's assertions are speculative and conclusory, akin to bald "the-defendant-unlawfully-harmed-me" allegations that were specifically considered – and rejected – by *Iqbal*. *See Iqbal*, 556 U.S. at 678—79.

Similarly, with regard to his failure-to-warn theory, the plaintiff must show that: (1) the warnings at issue were defective; (2) the defective warning made the product unreasonably dangerous; and (3) the inadequate labeling proximately caused the claimed injury. *McEelroy v. Amylin Pharm., Inc.*, No. 1:12-CV-297, 2013 WL 12099073, at *7 (E.D. Tenn. Aug. 5, 2013) (Mattice, J.), *aff'd McElroy v. Amylin Pharm., Inc.*, 573 F. App'x 545 (6th Cir. 2014); *Lee v. Metro. Gov't of Nashville & Davidson Cnty.*, 596 F. Supp. 2d 1101, 1127 (M.D. Tenn. 2009) (citing *Barnes v. Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005) (interpreting Tennessee law and holding: "An action based on an inadequate warning requires not only that the warning itself be defective, but that the plaintiff establish that the product is unreasonably dangerous by reason of defective warning and ... that the inadequate labelling proximately caused the claimed injury") (quotation and alteration omitted)). While the amended complaint alleges that the defendants failed to adequately warn plaintiff of various risks and characteristics of the mesh products [*see* Doc. 35 at ¶ 19], plaintiff has not sufficiently alleged facts to permit the Court to infer that either defendant's allegedly deficient warnings caused plaintiff's injuries.

Plaintiff's complaint also fails to allege facts for the Court to infer that the *condition* of the mesh products—based upon an alleged design or manufacturing defect—caused his alleged injuries. As Tennessee courts make clear, it is not enough that plaintiff suffered injuries from using (or in this case, having implanted) a product. *See, e.g.*, *Browder*, 541 S.W.2d at 404 (holding that in order to establish a product liability claim, the plaintiff must "trace the injury to some specific error in construction or design of the [product]"). Plaintiff must also allege "*how* the alleged defect(s) caused his injuries." *Fleming v. Janssen Pharm., Inc.*, No. 2:15-cv-02799-JPM-dkv, 2016 WL 3180299, at *7 (W.D. Tenn. May 6, 2016) (emphasis added). As noted above, the complaint only alleges that the plaintiff had the mesh products implanted in his body during a hernia repair surgery and that his "condition has worsened due to complications of one or both mesh products" [Doc. 35 at ¶ 13]. This conclusory statement, without any facts regarding the issue of causation, is insufficient to state a plausible claim for relief under Rule 12(b)(6). *See Iqbal*, 556 U.S. at 678.

Plaintiff argues that he does not have the "scientific understanding" of the products that the defendants do and therefore he should only be held to a pleading standard "commensurate with the information that is available to [him]" [Doc. 41 at pp. 8—9]. However, as defendants point out [Doc. 42 at p. 2; Doc. 43 at pp. 7—8], the information relevant to plaintiff's condition and the causes therefore are solely available to him. The defendants presumably have detailed information as to the characteristics of their products, but they have no information as to plaintiff's medical condition, the causes of his condition, or his prognosis. The *Twombly/Iqbal* standard requires the plaintiff to have greater

knowledge of those factual details in order to draft a plausible claim. *See New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011); *Weddle v. Smith & Nephew, Inc.*, No. 14 C 09549, 2016 WL 1407634, at *4 (N.D. Ill. Apr. 11, 2016) (plaintiff "has exclusive and complete access to her physicians and medical records, including records that report on the condition of the products used to stabilize [her ankle]"). Plaintiff is not entitled to discovery before he is required to set forth a plausible claim. *Iqbal*, 556 U.S. at 686.

In short, the amended complaint alleges that plaintiff had the defendants' mesh products implanted during a surgical hernia repair and that he has suffered unquestionably painful complications. However, the amended complaint fails to contain factual allegations that the mesh products were defective or unreasonably dangerous or that the defective or dangerous condition of the products were the proximate cause of his injuries. Because all of his claims are governed by the TPLA, Tenn. Code Ann. § 29-28-102(6), factual allegations supporting these essential elements are necessary for any of the claims to succeed.

Finally, it is worth making plain what both defendants argue. Plaintiff has asserted that "one or both mesh products" have caused his injuries [Doc. 35 at ¶ 13]. Plaintiff has not made specific allegations against each defendant or alleged the specific defect or dangerous condition of each product. *See Weddle*, 2016 WL1407634, at *3 ("the allegations against any particular defendant must plausibly allege liability based on that defendant's own conduct"). This lack of specificity is also fatal to his complaint.

IV. Conclusion

For the reasons set forth herein, the defendant's motions to dismiss [Docs. 37, 39] will be **GRANTED**. An appropriate order will be entered.

s/ Thomas W. Phillips
SENIOR UNITED STATES DISTRICT JUDGE